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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,419	06/07/2000	Tadashi Kohno	11127-002002	8455

7590

02/14/2002

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 02/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/589,419

Applicant(s)

KOHNO ET AL.

Examiner

D. L. Jones

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

CLARIFICATION OF RECORD

1. Having re-evaluated the restriction requirement mailed 9/18/01, Paper No. 5, it is believed that the restriction did not clearly set forth the various inventions disclosed in the instant invention. Thus, this Office Action is necessary in order to clarify the record.

RESTRICTION INTO GROUPS

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-10, drawn to a ¹³C-labeled oligosaccharide/polysaccharide excluding U-¹³C-maltose, ¹³C-starch, 1-¹³C-maltotetraose, and 1-¹³C-amylose, classified in class 424, subclass 1.73.
 - II. Claims 11-15, drawn to a ¹³C-inclusion complex that comprises cyclodextrin, classified in class 424, subclass 1.65.
 - III. Claims 16-21, 23, and 24, drawn to a method of diagnosing pancreatic function comprising administering ¹³C- or ¹⁴C-labeled oligosaccharide/polysaccharide other than ¹³C-starch, classified in class 424, subclass 9.1.
 - IV. Claim 22, drawn to a method of diagnosis pancreatic exocrine function comprising administering ¹³C- or ¹⁴C-labeled inclusion complex having cyclodextrin as a host molecule, classified in class 424, subclass 9.2.
3. The inventions are distinct, each from the other because of the following reasons:

Inventions (I and III) and (II and IV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compound/composition claims may or may not be used in the designated method claims. For example, Group I may be used with Group III; however, some of the compound excluded in Group I are not excluded in the method of Group II. Also, it is noted that the method claims are not only limited to ¹³C-labeled species as the compound/composition claims, but may include ¹⁴C-labeled species as well. Furthermore, since each group has different claim limitations, a different search is required. In other words, the species used in, for example, Group III, would not necessarily be anticipated or rendered obvious as it relates to Group I since the method claim does not exclude the same species of Group I and includes ¹⁴C-labeled species.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

ELECTION OF SPECIES

5. Claims 1-24 are generic to a plurality of disclosed patentably distinct species comprising diagnostic agents. In particular, the invention is directed to ¹³C-labeled

oligosaccharides or polysaccharides excluding U-13C-maltose, 13C-starch, 1-13C-maltotetraose; and 1-13C-amylose; a 13C-labeled inclusion complex comprising cyclodextrin or a derivative thereof; a method of diagnosing pancreatic exocrine function using 13C- or 14C-labeled oligosaccharides or polysaccharides other than 13C-starch; and a method of diagnosing pancreatic exocrine function by administering a 13C- or 14C-labeled inclusion complex having cyclodextrin or a derivative thereof. Applicant is required under 35 U.S.C. 121 to **elect a single disclosed species**, even though this requirement is traversed.

Note: Applicant is respectfully requested to elect a single species for prosecution from the elected group above.

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Art Unit: 1616

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


D. L. Jones
Primary Examiner
Art Unit 1616

February 7, 2002